Clinical Trials Management Systems Workspace
Face-to-Face Meeting
Oregon Health & Science University

SESSION: C3PRv2 Release 2.0 Functional Deep Dive

Session Information	**Date: May 31, 2007** **Time: 1:30 p.m. – 3:00 p.m. PDT** **Presenter/Lead: Patrick McConnell, Duke University (project lead architect)** **Facilitator: Niket Parikh** **Scribe: Karen Ryan**
Executive Summary	Patrick McConnell presented on the Cancer Central Clinical Participant Registry version 2 (C3PRv2) project development summary, timelines, and differences between Release 1 and Release 2. C3PRv2 tracks subject registration, randomization, stratification, integration with other clinical systems, and support for multi-site studies (C3PR-to-C3PR integration); extends registration; enhances protocol management by providing web-based access; and augments reporting to meet regulatory needs. Development did include a diverse group of elaborators, resulted in a secure self-sufficient system, and leveraged the Biomedical Research Integrated Domain Group (BRIDG) model during development. An export feature (data into XML files) is provided, but some sites may want to build a custom program to export from their own legacy participant registry systems.
Discussion	C3PRv2 was demonstrated, showcasing each of the four modules: *Registration, Studies, Subjects,* and *Administration*. The demonstration was interactive, providing for feedback and questions throughout.
Requirements	

Req. #	Name	Description
1	Role management	C3PRv2 may need to provide generic roles assigned to a user login or provide for a system-wide registrar. Auditing issues remain. Groups being developed are based on roles and activities. No generic users will be created, i.e., full accountability is associated with the user account, and accounts must be associated with a person.
2	User interface (human factor)	Increasing the font size at the browser level has some adverse impacts. Developers will look into it. The user interface (UI) for the cancer Adverse Event Reporting System (caAERS) handles this well—plans are to adopt a similar UI in C3PRv2. Clinical Trials Management Systems Interoperability (CTMSi) needs to drive some of these user interface initiatives for standardized use among CTMS applications.
3	Harmonizing list of roles	A preliminary list of roles has been compiled from the recent C3PRv2 F2F, but roles are already defined in Cancer Data Standards Repository (caDSR). Developers will need to harmonize their roles with the roles defined in the caDSR and BRIDG.

4	Data entry responsibility with multi-site studies	"Organizational responsibilities" need to be looked into overall. Coordinating centers will likely have more responsibility regarding the data and the participating sites will not have as much responsibility. C3PR v2 aims to create a separate workflow/wizard for coordinating centers.
5	Interoperability issue with Epochs and Arms	Patient Study Calendar (PSC) to C3PRv2 interoperability must move between Epochs and Arms.
6	Duplicate entry of subjects	Developers are implementing logic to aid in identifying potential duplicates at the time of entry.
7	Patient IDs	Study subject IDs need to be synchronized with the coordinating site. Sites differ in their process so the developers should look into the need for tracking the other sites' patient IDs during the registration process.
8	Reporting features	Developers confirmed that they are looking into various reporting capabilities, including current accruals, etc.

Issues

Issue ID	Description
1	Are there plans to allow import of protocol information from another system? Yes, there are plans to provide application programming interfaces (API) and to provide batch loading options (via XML and Excel) to do so as well.
2	Can any one person have more than one role? No, however, the developers are looking into providing this flexibility.
3	Is there skip logic built into C3PRv2 (eligibility or stratification)? No, every question must be answered.
4	The need for a protocol abstraction system was apparent during demonstration of the study creation module of C3PRv2. It was understood that C3PRv2 would not be "the source of truth" for protocol definitions. It was reiterated that the application needs a core set of protocol information set up within its repository so that the subjects can be registered. C3PRv2 will be integrated with the protocol management system once the latter is available.
5	How are mistakes in patient enrollment corrected? Only by role-specific authorities—the user (registrar) will need to go to someone with the right authority (site coordinator).

Action Items

Assigned To	Description	Due Date

Attendance

#	First Name	Last Name	Affiliation
1.	Christo	Andonyadis	NCI CBIIT
2.	Bob	Annechiarico	Duke
3.	Ram	Chilukuri	Semantic Bits

4.	Cal	Collins	Akaza
5.	Doug	Fridsma	University of Pittsburgh
6.	Amy	Funkhouser	ECOG
7.	Meg	Gronvall	Booz Allen Hamilton
8.	Robin	Harris	Arizona
9.	Smita	Hastak	ScenPro
10.	Kim	Johnson	CALGB
11.	Warren	Kibbe	Northwestern
12.	Jack	London	Kimmel Cancer Center
13.	Brenda	Maeske	SAIC
14.	Bob	Morrell	WFU
15.	Niket	Parikh	Booz Allen Hamilton
16.	George	Redmond	NCI / CTEP
17.	Dianne	Reeves	NCI CBIIT
18.	Karen	Ryan	Booz Allen Hamilton
19.	Peter	Schad	NCI / DCCPS
20.	Angela	Smith	SWOG
21.	Rhett	Sutphin	Northwestern
22.	Umit	Topaloglu	UAMS
23.	Troy	Walls	UAMS
24.	Sean	Whitaker	Northwestern